K040882

JUN 1 0 2004

BIOMÉRIEUX

Section H. **510(k) Summary**

Applicant Name and Address

Applicant:	bioMerieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Sandra Perreand
Phone Number:	(314) 731-8594
Fax Number:	(314) 731-8689
Date of Preparation:	March 22, 2004

Device Name

Trade Name:	VIDAS D-Dimer New (DD2) Assay
Common Name:	Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of fibrin degradation products (FbDP)
Classification Name:	Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control

Predicate Device

Trade Name:	VIDAS D-Dimer (DD) New Assay, K020810

Device Description

The VIDAS® D-Dimer New (DD2) Assay is an automated quantitative test for use on the VIDAS instrument (K891385) for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma using the enzyme-linked fluorescent immunoassay (ELFA) technique. The instrument controls all assay steps and assay temperatures. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed DD2 Reagent Strips.

Intended Use

The VIDAS® D-Dimer New is an automated quantitative test for use on the VIDAS analyzer for the immunoenzymatic determination of fibrin degradation products (FbDP) in citrated human plasma using the ELFA techniques (Enzyme Linked Fluorescent Assay). The VIDAS® D-Dimer New assay is indicated for use in conjunction with a clinical Pre-test Probability Assessment (PTP) model in excluding deep venous thrombosis (DVT) and Pulmonary Embolism (PE).

Technological Characteristic Summary

Summary of Similarities and Differences to Predicate Device

Major Similarities Include:

1) The VIDAS D-Dimer assays are identical except for the proposed modification in the Indications for Use.

Major Differences Include:

1) The major difference between the two VIDAS assays is that we are expanding the indications for use for the assay.

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Performance Data

Data from a three site prospecitive patient management study was presented. The results were as follows:

The observed sensitivity, specificity, PPV and NPV (with exact 95% Confidence Intervals) and prevalence for all PE suspected patients (n=965) from all sites and all pre-test probability scores combined are shown below. The prevalence of PE was 23.0 %.

VIDAS D-Dimer Performance-All Sites (Overall prevalence of PE= 23.0 %)

All Patients	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
965	100 % (98.4-100%)	37.7 % (34.2-41.3%)	**100 % (98.7-100%)**	32.4 % (28.9-36.1%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	222	463	685
(-) D-dimer	0	280	280
Total	222	743	965

The observed sensitivity, specificity, PPV and NPV (with exact 95% Confidence Intervals) and prevalence for all PE suspected patients (n=965) from all sites combined by pre test probability are shown below.

Low and intermediate (moderate) pre test probability- Prevalence of PE= 17.8 %

Low & Intermediate	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
891	100 % (97.7-100%)	37.6 % (34.0-41.2%)	**100 % (98.7-100%)**	25.8 % (22.4-29.5%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	159	457	616
(-) D-dimer	0	275	275
Total	159	732	891

High pre test probability- Prevalence of PE= 85.1 %

High	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
74	100 % (94.3-100%)	45.5 % (16.7-76.6%)	**100 % (47.8-100%)**	91.3 % (82.0-96.7%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	63	6	69
(-) D-dimer	0	5	5
Total	63	11	74

D. VIDAS D-Dimer Performance-By Site

The observed sensitivity, specificity, PPV and NPV (with exact 95% Confidence Intervals) for PE suspected patients **by site** are shown below.

Site 1- Angers University Hospital, Angers, France- Prevalence of PE= 21.5 %

All Patients	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
284	100 % (94.1-100%)	38.1 % (31.7-44.8%)	**100 % (95.8-100%)**	30.7 % (24.3-37.6%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	61	138	199
(-) D-dimer	0	85	85
Total	61	223	284

Site 2- Geneva University Hospital, Geneva, Switzerland -Prevalence of PE= 20.5 %

All Patients	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
430	100 % (95.9-100%)	38.6 % (33.4-44.0%)	**100 % (97.2-100%)**	29.5 % (24.4-35.1%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	88	210	298
(-) D-dimer	0	132	132
Total	88	342	430

Site 3- University Hospital, Lausanne, Switzerland-Prevalence of PE= 29.1 %

All Patients	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)	% PPV (95% CI)
251	100 % (95.1-100%)	35.4 % (28.4-42.9%)	**100 % (94.3-100%)**	38.8 % (31.8-46.2%)

VIDAS D-Dimer	PE (+)	PE (-)	Total
(+) D-dimer	73	115	188
(-) D-dimer	0	63	63
Total	73	178	251

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 0 2004

Ms. Sandra Perreand
Director, Regulatory Affairs
Biomerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042

Re: k040882
Trade/Device Name: VIDAS D-Dimer Exclusion Assay
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP
Dated: April 2, 2004
Received: April 5, 2004

Dear Ms. Perreand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: VIDAS D-Dimer Exclusion Assay

Indications for Use:

The VIDAS® D-Dimer Exclusion assay is an automated quantitative test for use on the VIDAS analyzers for the immunoenzymatic determination of fibrin degradation products (FbDP) in citrated human plasma using the ELFA techniques (Enzyme Linked Fluorescent Assay). The VIDAS® D-Dimer Exclusion assay is indicated for use in conjunction with a clinical Pre-test Probability Assessment (PTP) assessment model to exclude deep venous thrombosis (DVT) and pulmonary embolism (PE) in outpatients suspected of DVT or PE.

Prescription Use **XX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040882